REMARKS

Summary of Office Action

Examination of claims 11-13, 15-18, 21-26, 32, 33, and 47 is reported in the present Office Action. Claims 11-13, 15-18, and 22-26 are rejected under 35 U.S.C. § 112, first paragraph. Claims 21, 32, 33, and 47 are rejected under 35 U.S.C. 103(a). Each of the rejections is addressed below.

Summary of Invention

The invention generally features nucleic acid sequences having 99% identity to SEQ ID NO:5, which encodes an immunomodulatory polypeptide (SEQ ID NO:4), and cells and vectors containing such sequences.

Support for the Amendment

Support for the amendment of claim 11, and its dependent claims, and for new claims 58-62 is found throughout the specification and claims as originally filed; for example, support for the amendment of claim 11, which now recite "modulates mammalian immunosuppression, immunostimulation, inflammation, cell proliferation, or apoptosis, or decreases T cell stimulation or inflammation," is found at page 7, lines 23-25. Support for new claims 58-62 is found at SEQ ID NOs: 4 and 5.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 11-13, 15-18, 22-26 were rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement, because undue experimentation would be required to identify nucleic acid sequences that have 99% identity to SEQ ID NO:5 and encode a polypeptide having immunomodulatory function. In support of this rejection, the Examiner asserts that the term "immunomodulatory" does not provide a specific function for the protein encoded by SEQ ID NO:5, because any protein that is injected into a mammal is immunomodulatory. As detailed below, this rejection is overcome by the amendment of the claims, which now recite a polypeptide having particular immunomodulatory effects, specifically, a polypeptide that modulates mammalian immunosuppression, immunostimulation, cell proliferation, apoptosis, or decreases T cell stimulation or inflammation.

The standard for enablement is whether a person skilled in the art can make and use the invention without undue experimentation. (In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Applicants have clearly satisfied this standard. Methods for assaying the immunomodulatory effects of a polypeptide are known in the art and are described in applicants' disclosure. For example, applicants teach that immunomodulators may be characterized in animal models of acute inflammation (page 36, lines 16-24), in rat, mouse, or rabbit models of arthritis (page 36, line 25, to page 38, line 4), in rat, rabbit, or monkey models of transplant rejection (page 38, line 6, to page

39, line 17); in a rat model of reperfusion injury; in a rat or mouse model of asthma (page 40, lines 5-20); in mouse or rat models of inflammatory bowel disease (page 40, lines 21, to page 41, line 11); and in a mammalian model of uveitis. Such models may be used to assay for immunostimulation or immunosuppression, i.e., an increase or decrease in the overall immunoreactivity of an immune system (page 20, line 27, to page 21, line 5). The level of T cell stimulation is another measure of immunoreactivity. A decrease in T cell stimulation in response to an immunomodulator can be measured using a chromium release assay (page 21, lines 3-6).

Other immunomodulatory effects, such as inflammation, can be assayed by measuring the number of inflammatory cells in a target tissue (page 21, lines 6-8). A decrease in the number of leukocytes, for example, indicates a decrease in inflammation. Such a decrease may result from an increase in apoptosis, as characterized by cytolemmal blebbing, cell soma shrinkage, chromatin condensation, and DNA laddering (page 21, lines 9-12). Alternatively, the number of such cells may increase due to an increase in cellular proliferation (page 21, lines 8-10).

In view of the above teachings in the specification, it is clear that applicants have enabled methods of assaying a polypeptide encoded by a nucleic acid having 99% identity to SEQ ID NO:5 for its ability to modulate mammalian immunosuppression, immunostimulation, T cell stimulation, inflammation, cell proliferation, or apoptosis as presently claimed. Such assays could easily be carried out using methods available at the

time of filing and disclosed in applicants' specification. Accordingly, the enablement rejection should be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 22, 32, 33, and 47 were rejected as obvious over Lee et al. (Studies of Yaba-like disease virus, a yatapoxvirus, Thesis, September 25, 2000; and Gene Bank Sequence, AJ293568) in view of Hooper et al., (U.S. Patent No. 6,562,376). While applicants disagree with the present rejection, in order to expedite prosecution applicants have cancelled claims 22, 32, 33, and 47. Thus, the obviousness rejection should also be withdrawn. Applicants reserve the right to pursue the rejected subject matter in a continuing application.

New Claims

New claims 59-62 are directed to nucleic acid molecules comprising SEQ ID NO:5 or encoding a polypeptide comprising SEQ ID NO:4. It is applicants' understanding that the Examiner has indicated that the claimed subject matter is allowable, and such action is respectfully requested.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. If the Office does not concur, a telephonic interview with the undersigned is hereby requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Enclosed is a Petition to extend the period for replying to the final Office action for three months, to and including June 19, 2004. Also enclosed is a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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